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October 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Regarding: Docket No. 98D-0969

Dear Sir or Madam:

Although I wasn't able to attend the general public meeting to give input to the FDA on the appropriate issues, experts, and agenda items to be included in the next two scientific workshops on antimicrobial resistance, I would like to submit comments on the process of designing these meetings.

From what I have heard of the way the October 4 public input meeting was conducted, I am very concerned about the process that FDA is using to gather feedback. I understand the necessity of the FDA to give all interested stakeholders the opportunity to offer their ideas. However, offering the participants just a few minutes to present them leads to some question about the effectiveness of the process. Without the opportunity for discussion there would be little opportunity for meaningful exchange of ideas. It certainly leads to the appearance that the FDA has a preconceived notion of how it will conduct the next two meetings and whom it will invite to participate. Without allowing for more substantial input, one might conclude that the FDA is following a European model by holding up an inconsequential input meeting as evidence that it has gathered stakeholders' ideas when the final agenda has already been determined.

I would recommend that the FDA follow the precedent set by the development of the Veterinary Feed Directive and the USDA-FSIS efforts to form the Hazard Analysis and Critical Control Point (HACCP) regulations. During these series of meetings, serious discussions were held in which the participants could offer and debate their views and opinions. In this way, all the stakeholders had a hand in the outcome

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and felt like they owned the process. Dr. Sundlof even commented during the VFD meetings that the VFD process was so successful that it should be used as a template for addressing future drug issues. FDA should heed these words and now follow that advice.

USDA-FSIS published a Federal Register Notice on January 11, 1994 (Docket No. 93-024N) in which it announced a Round Table process to "At the Secretary's direction to ensure greater input from all constituent and other interests . . . to provide . . . a forum to comment on development of a mandatory HACCP system." [Attachment No. 1] The USDA-FSIS allowed, in their words, "a substantive opportunity to assist FSIS through a thorough discussion of the issues regarding HACCP" through the formation of a Steering Committee, the identification of the stakeholders, the identification of the issues that needed to be addressed, and by conducting a Round Table opportunity to discuss and reach consensus on the issues. This is not unlike the challenges and opportunities that we face as we address the issues brought forth by the FDA's Framework document.

During the HACCP regulation input gathering process, the HACCP Steering Committee met and set the guidelines for the Round Table meeting. Meeting facilitation and structure, role of the media, input from observers, handouts, materials, and background documents available at and previous to the Round Table, the set up for the meeting room, and other pre-meeting activities were all discussed by the Steering Committee and provided an organized, well prepared structure for the Round Table discussions of its contentious topics. The Steering Committee developed an Issues Background document that identified and prioritized major Round Table subject areas. [Attachment No. 2] The substantive content of this document and the Steering Committee's work was then published in the Federal Register on March 24, 1994, Docket No. 94-009N. [Attachment No. 3]

Finally, before the Round Table USDA-FSIS prepared a HACCP Round Table Key Issues document that served as a template for the Round Table breakouts and discussions. This document gave a Background Statement, Issue Statement, Questions, and Discussion points for each of the Steering Committee prioritized issues for the Round Table participants. [Attachment No. 4]

A plan for the Framework discussions should include the best qualities of the VFD and HACCP input processes. It should allow thoughtful and meaningful input to the FDA through building coalitions and reaching consensus. In spite of the public statements from the CDC, consensus on these issues **is** critical to gain ownership and reach meaningful, effective conclusions that are in the best interest of the public health.

Because the resolution of these issues will have profound effects on animal agriculture, its allied industries, and ultimately the public, it is imperative that they be given every opportunity to be carefully and fully considered. We all want to see timely progress, but it is more important that the process is done correctly than that it is done quickly. We need to proceed but we need to do so without a rush to judgement. The numerous commissions and expert reports on antimicrobial resistance are consistent in the view that although there may be some public health concern from agricultural antimicrobial use the risk is not imminent.

Thank you for your consideration of these comments. On behalf of the pork industry, we stand ready to assist the FDA in reaching carefully considered, science-based resolutions to the many antimicrobial resistance issues.

Sincerely,

Paul Sundberg DVM

Paul Sundberg, DVM, PhD
Assistant Vice-president, Veterinary Issues
National Pork Producers Council

[Federal Register: January 11, 1994]

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

ATTACHMENT NO. 1

9 CFR Chapter III

[Docket No. 93-024N]

Hazard Analysis and **Critical Control Point Round Table**; Solicitation of Participation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Solicitation of participation.

SUMMARY: Secretary Espy announced in late May 1993 that he was requesting the Food Safety and Inspection Service (FSIS) to present him with a plan for making the **Hazard Analysis** and **Critical Control Point** (HACCP) system of process **control** mandatory in all the Nation's federally inspected meat and poultry establishments. At the Secretary's direction to ensure greater input from all constituent and other interests, it was determined by FSIS that it would be beneficial to provide all constituent groups with a forum to comment on development of a mandatory HACCP system. Therefore, FSIS announces that a HACCP **Round Table** discussion will be held.

This notice outlines the **Round Table** process and solicits participation in the **Round Table** from the constituent groups identified below in the SUPPLEMENTARY INFORMATION. Furthermore, this notice offers the opportunity for persons who believe that an affected interest is not represented below to request participation at the **Round Table**.

DATES: A HACCP **Round Table** discussion will be held in about 60 days of the date of publication of this notice in the Federal Register. Individuals and organizations interested in participating in the **Round Table** must submit their names by January 25, 1994.

ADDRESSES: Interested persons should submit their names to Mr. Mark Manis, Director, Import Inspection Division, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, room 0114, South Building, 14th and Independence Avenue, SW., Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT:
Mr. Mark Manis at (202) 720-2952.

SUPPLEMENTARY INFORMATION: FSIS views this **Round Table** as an opportunity to allow free and frank discussion of the legitimate concerns of all constituents prior to the issuance of a proposed regulation on HACCP. This meeting is envisioned as a substantive opportunity to assist FSIS through a thorough discussion of the issues regarding HACCP. This will aid FSIS when it begins drafting the rule for implementing a HACCP system of production in all meat and poultry establishments.

The **Round Table** will be facilitated by a neutral third party. The facilitator will seek the full participation of all **Round Table** participants, will ensure that all identified issues are addressed by the **Round Table** participants, and will invite comments at the end of the **Round Table**. After the **Round Table** meeting, the facilitator will

provide a transcript of the meeting, and will prepare a final report, which will include any comments submitted at the **Round Table** meeting and will summarize the positions of all **Round Table** participants.

The **Round Table** meeting will be open to the public. Issue papers will be prepared in advance of the meeting by the participants, and will be publicly available through the FSIS hearing clerk. All issues relative to a HACCP system shall be open for consideration.

FSIS has preliminarily identified the following categories of constituents:

<bullet> Meat and Poultry Industry and Their Representatives (Including Grocers and Retailers)
<bullet> Consumers and Their Representatives
<bullet> Scientists and Professional Scientific Organizations
<bullet> Producers and Farmers
<bullet> FSIS Employees and Their Representatives
<bullet> Federal, State, and Local Governments
<bullet> Public Health Officials and Medical Doctors

Any individual or organization that is interested in participating in the **Round Table** must communicate that interest, and identify his or her constituent category, to Mr. Mark Manis whose address and phone number appear in this notice in the paragraph entitled FOR FURTHER INFORMATION CONTACT, within 2 weeks of the date of the publication of this notice in the Federal Register. After the 2-week notification period, FSIS will: (1) Compile a list, for each category, of those who expressed an interest in participating in the **Round Table** meeting; and (2) share that list, by category, with the members of each category. FSIS will then request, within 2 weeks after sending the list to members of each category, that the members of each category select representatives to serve as both **Round Table** and Steering Committee participants.

To ensure the effectiveness of this process, the estimated number of **Round Table** participants will be between 25 and 30, and the total number of attendees will be determined by the capacity of the meeting room. FSIS will request each constituent category to appoint one representative to serve on the Steering Committee. FSIS will request that five representatives be appointed for the **Round Table** by each of the following constituent categories: Meat and Poultry Industry and Their Representatives; Consumers and Their Representatives; and Scientists and Professional Scientific Organizations. FSIS will request that four representatives be appointed for the **Round Table** from the Producers and Farmers category. FSIS will request that three representatives be appointed for the **Round Table** from the FSIS Employees and Their Representatives; and Federal, State, and Local Governments categories. FSIS will request that two representatives be appointed for the **Round Table** from the Public Health Officials and Medical Doctors category.

If any constituent category is unable to designate its representatives, USDA will assist in the selection.

Furthermore, any person who believes that an affected interest is not represented by the identified categories of constituent groups may request, within 2 weeks of the date of publication of this notice in the Federal Register, **Round Table** participation for that affected interest.

Once the representatives are appointed, FSIS will convene a Steering Committee to be held in the Washington, DC, area in advance of the **Round Table** meeting. The Steering Committee will address all relevant pre-meeting issues and determine the: (1) **Round Table** issues; (2) process for developing issue papers prior to the **Round Table**; (3) timeframes; (4) meeting schedule; (5) **Round Table** discussion rules; and (6) any other matter which would assist in an effective and full discussion.

Done at Washington, DC, on: January 5, 1994.
H. Russell Cross,
Administrator, Food Safety and Inspection Service.

[FR Doc. 94-556 Filed 1-10-94; 8:45 am]
BILLING CODE 3410-DM-M

BACKGROUND: ROUND TABLE ISSUES

The Steering Committee focused on four major subject areas: 1) Design and Scope; 2) Industry and Government Roles and Responsibilities; 3) In - Plant Implementation; and 4) Impact, Evaluation and Communication.

Each of these major subject areas could require at least two days of deliberation. Therefore, in order to utilize time most effectively during the two day Round Table the steering committee established criteria for prioritizing the several issues identified within each major category.

The key issues were determined on the basis of the following priorities:

1. Importance in shaping the HACCP rule.
2. Apparent absence of agreement among constituent groups on the direction the Agency should take.
3. Issues most likely to help the Agency to deal effectively with a proposed rule.

The following issues were identified for each of the four major subject areas (the six key issues are denoted by an asterisk):

I. Design and Scope
   1. Mandatory/Voluntary
   2. Safety/Safety and Economic
   3. Application to All Processes
   4. Seven HACCP Principles
   5. Limit HACCP to In-Plant Focus

II. Industry/Government Responsibilities
   1. HACCP Plan Development
   * 2. HACCP Plan Approval
   3. Government/Industry Role in Relation to Seven Principles
   * 4. Training/Certification

III. In-Plant Implementation
   * 1. Phase In (pilots, across the board, high risk, incentives, government assistance to plants)
   2. Cost/Benefit

IV. Impact, Evaluation, and Communication
   * 1. Measures of Effectiveness
   * 2. Compliance/Enforcement
   * 3. Relationship and Effect of HACCP on Current Inspection Program
   4. Expectations/Reality

On the basis of the process of prioritization described above, the steering committee identified the following six key issues which will be addressed during five separate sessions at the Round Table:

1) HACCP Plan Approval
2) Training/Certification
3) Phase In
4) Measures of Effectiveness
5) Compliance/Enforcement
6) Relationship and Effect of HACCP on Current Inspection Program.

If the Round Table participants are able to move through these six priority issues, then they should proceed to address any other issues.

[Federal Register: March 24, 1994]

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DEPARTMENT OF AGRICULTURE

ATTACHMENT NO. 3

Food Safety and Inspection Service
[Docket No. 94-009N]

Hazard Analysis and **Critical Control Point** (HACCP) **Round Table** Meeting

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: On January 11, 1994, Secretary Espy announced in the Federal Register his intention to hold a **Hazard Analysis** and **Critical Control Point** (HACCP) **Round Table** session. The process for the **Round Table** was outlined whereby constituents and other interests could notify FSIS of their desire to participate in the meeting. This notice provides: (1) The names of the participants in the **Round Table**, (2) the names of the **Round Table** Steering Committee members, and (3) the site of the **Round Table**.

DATES AND PLACE: The **Round Table** will be held on March 30 and 31, 1994, at the Hyatt Regency Hotel, 400 New Jersey Avenue NW., Washington, DC. The meeting will commence at 8:30 a.m. each day.

FOR FURTHER INFORMATION CONTACT:
Mr. Mark G. Manis, Director, Import Inspection Division, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 0114, South Building, 14th and Independence Avenue SW., Washington, DC, (202) 720-2952.

SUPPLEMENTARY INFORMATION: FSIS views the **Round Table** as an opportunity to allow free and frank discussion of the concerns of constituents prior to the issuance of a proposed HACCP regulation. The meeting is viewed as an opportunity to assist FSIS through a thorough and substantive discussion of the issues regarding HACCP. FSIS welcomes the views of the participants as well as those of the observers of the meeting.

The following individuals will serve as **Round Table** participants:

Meat and Poultry Industry and Their Representatives
1. Kenneth May, National Broiler Council
2. Tim Brown, Kroger Company
3. Gary Kushner, Hogan and Hartson
4. Bruce Tompkin, Armour Swift-Eckrich
5. Bernard Hansen, Flint Hills Foods, Inc.

Consumers and Their Representatives
6. Carol Tucker Foreman, Safe Food Coalition
7. Caroline Smith DeWaal, Public Voice for Food and Health Policy
8. Gerald F. Kuester, Safe Tables
9. Karin L. Bolte, National Consumers League
10. Thomas Devine, Government Accountability Project

Scientists and Professional Scientific Organizations
11. Dane Bernard, National Food Processors Association
12. John Troller, American Society for Microbiology
13. Richard H. Forsythe, University of Arkansas
14. James Marsden, American Meat Institute

15. Michael Doyle, University of Georgia
Producers and Farmers
16. Beth Lautner, National Pork Producers Council
17. Robert A. Smith, Oklahoma State University
18. Rod Bowling, National Cattlemen's Association
19. Michael Robach, Wayne Poultry
FSIS Employees and Their Representatives
20. Edward Menning, National Association of Federal Veterinarians
21. Arthus Hughes, National Joint Council
22. Dennis Reisen, Association of Technical and Supervisory Professionals
Federal, State, and Local Governments
23. Martha R. Roberts, Florida Department of Agriculture and Consumer Services
24. Mike Windham, National Association of State Departments of Agriculture
25. Michael Mamminga, National Association of State Meat and Food Inspection Directors
Public Health Officials
26. Pamela V. Fernandez, Americçan Public Health Association
27. George Dimmick, Indiana State Department of Health
Other Participants
28. George Bancroft, Bancroft Farms
29. Edna Carpenter, Western Resource Council
30. LeRoy Russ, Carl Karcher Enterprise
31. Fred R. Shank, Food and Drug Administration, HHS
32. Lonnie J. King, Animal and Plant Health Inspection Service, USDA
33. Mark G. Manis, Food Safety and Inspection Service, USDA

The following **Round Table** participants are also members of the Steering Committee:

1. Dane Bernard
2. Carol Foreman
3. Arthur Hughes
4. Beth Lautner
5. Mark Manis
6. Kenneth May
7. Edward Menning
8. Dennis Reisen
9. Martha Roberts

The Steering Committee met in Washington, DC, on March 8 and 9, 1994. The committee prepared the following statement.

HACCP **Round Table** Purpose

The purpose of the **Round Table** is to provide a forum for issues involved in the development and implementation of a mandatory HACCP program that will improve the safety of meat and poultry products. The goals of the **Round Table** are to: 1) identify issues of concern; 2) explore possible areas of agreement and disagreement; and 3) identify measures that will facilitate implementing a preventive system of **control** by providing input to FSIS prior to rulemaking.

Furthermore, the Steering Committee identified six key issues for the **Round Table**: 1) HACCP Plan Approval; 2) Measures of Effectiveness; 3) Compliance/Enforcement; 4) Relationship and Effect of HACCP on Inspection Procedures; 5) HACCP Training; and 6) Phase-In of Mandatory HACCP. The Steering Committee participated in the drafting of issue papers for these six issues. The six issue papers will be available in advance of the meeting and can be obtained from Mr. Manis. The consideration of other issues either orally or in writing will be entertained at the **Round Table**. If written material is presented, then one copy must be furnished for the record.

The **Round Table** will be open to the public, and a transcript will

be prepared of the meeting. A final report, which will include any comments submitted at the **Round Table**, will be prepared and made available to the public.

Done at Washington, DC, on: March 17, 1994.
Patricia Jensen,
Assistant Secretary, Marketing and Inspection Services.
[FR Doc. 94-6862 Filed 3-23-94; 8:45 am]
BILLING CODE 3410-DM-M

HACCP ROUND TABLE

KEY ISSUES

1. HACCP PLAN APPROVAL

2. TRAINING/CERTIFICATION

3. PHASE IN

4. MEASURES OF EFFECTIVENESS

5. COMPLIANCE/ENFORCEMENT

6. RELATIONSHIP AND EFFECT OF HACCP ON INSPECTION PROCEDURES

I. HACCP PLAN APPROVAL

BACKGROUND STATEMENT:

HACCP plans should meet all seven HACCP principles for preventive control of food hazards. The seven HACCP principles are: 1) conduct a hazard analysis; 2) identify the critical control points in the process; 3) establish critical limits; 4) establish critical control point monitoring requirements; 5) establish corrective action plan; 6) establish record-keeping procedures; and 7) establish verification procedures. After the plan is designed and before it is implemented it must be reviewed to assure that it meets the accepted criteria.

ISSUE STATEMENT:

What is the best way to ensure that HACCP plans effectively incorporate the seven HACCP principles?

QUESTIONS:

1. Is it possible to develop criteria or checklists which would readily indicate whether the HACCP principles were adequately embodied in a given plan? Who should do this? Can this be done in such a way that it is not an additional paperwork burden?

2. Are there other means of ensuring that HACCP principles are adequately embodied in the HACCP plans?

3. Where does expertise currently exist which could be used to judge the validity of HACCP plans? For example, do universities, processing authorities, professional associations, or others, have this expertise? How can these sources be brought to bear on this issue?

4. In determining whether HACCP plans are satisfactory, is there a role for either on-site observation or a trial period during which HACCP records are maintained and some finished product testing results are made available?

DISCUSSION:

Meat and poultry establishments are in the best position to develop their HACCP plans because they have specific knowledge of the products they produce. Also, they are familiar with the variability and limitations of their plant's operation.

Plants need to apply their experience and knowledge in the development of their HACCP plans. Nevertheless, FSIS wants to be certain that the HACCP plans embody the HACCP principles in order to assure that food safety problems are prevented from occurring.

The issue of establishing criteria for acceptable HACCP plans can be separated from who should approve the plans. One consideration is whether there is sufficient guidance currently available, and accepted, that articulates HACCP plan acceptability.

Plan approval can be considered from three broad alternatives: self approval; third party approval; and FSIS approval. First, self approval suggests that the plant assumes responsibility for ensuring that the plan conforms to all requirements. A plant could seek outside expertise, but ultimately the plant is responsible.

Second, third party approval implies that some external, from the plant, approver ensures that the HACCP plans are acceptable. The approach raises questions about how the third party will be defined, and who would approve the third party. Does the third party need to be recognized as having a specific body of knowledge, and if so how will that be determined. Furthermore, what degree of autonomy should exist between the third party and the plant it is reviewing.

Third, FSIS headquarters approval allows for more uniformity in application of requirements, with a greater concentration of technical expertise. The FSIS field inspection workforce is widely dispersed, and the in-plant workforce will be trained to enhance its knowledge of HACCP. There is the possibility of either field approval or headquarters approval.

The question of site approval concerns the relationship between a document, the HACCP plan, and the reality of the activities actually occurring in the plant. Can the approving authority assure that the HACCP plans are effective without comparing the written plan with the plant operations.

Also, there is the question of approval of state plants. Essentially the same three alternatives listed above could be applied to the question of HACCP plan approval at the state level.

II. TRAINING/CERTIFICATION

BACKGROUND STATEMENT:

In both the regulated industry and among FSIS employees, there is a significant need for training in HACCP in order to ensure proper implementation. FSIS takes full responsibility for training its own workforce; in addition, FSIS believes it is important that there be developed between itself and the industry and within the industry, a common understanding of HACCP principles and practices.

ISSUE STATEMENT:

What should be the role of FSIS with regard to industry HACCP training?

QUESTIONS:

1. What group(s) should participate in determining the scientific and technical content of HACCP training?

2. What mechanisms are or could be made available to accomplish this?

3. What is the best way to assure that companies have adequate training/expertise to be able to operate a HACCP system?

4. There have been successful, if limited, applications of HACCP principles to specific products, such as the regulation of low-acid canned foods. Do the training aspects of these experiences offer models which can be useful as we try to implement HACCP?

5. How can the training needs of difficult-to-serve groups--small companies with few staff, remotely located companies, etc.--be accommodated?

6. There is some suggestion that common training for company employees and the in-plant inspection work force is beneficial. How could this concept be applied?

7. What should be done about individuals who have already received HACCP training and are, in fact, demonstrating their knowledge on a routine basis in their company's operations?

DISCUSSION:

Training is one vehicle through which the agency can assure that HACCP is uniformly and appropriately applied in inspected establishments. It will not be a useful vehicle, however, unless the agency has some means to be reasonably confident that HACCP training programs are focussed correctly and that those who complete HACCP courses have the requisite knowledge to put it to work in an establishment.

FSIS is not a leading expert either on HACCP or on methods of education. Therefore, it must devise other means to satisfy itself that training is adequately preparing industry personnel for their roles in this process control system. FSIS also needs to ensure that its training agenda and methods are not at cross-purposes with those of its other regulatory partners, such as the Food and Drug Administration.

III. PHASE IN

BACKGROUND STATEMENT:

FSIS regulates more than 7000 meat and poultry establishments across the country. Mandatory HACCP requirements will necessitate significant changes in each of those establishments; further, the changes to be made in each establishment may not be identical. The FSIS workforce will be receiving training during the pendency of the mandatory regulation and during what is expected to be a lengthy period between the final regulation and the effective date.

ISSUE STATEMENT:

Should the mandatory HACCP requirement be phased-in, and if so, how?

QUESTIONS:

1. The mandatory HACCP requirement could be phased in based on relative risk of the processes to be controlled; is this a viable idea? Should products with more or less risk be phased in first?

2. The mandatory HACCP requirement could be phased in based on existing industry experience; that is to say, companies which already have HACCP systems might be phased in first (or last). What are the advantages and disadvantages of such an approach?

3. Should phase in be mandated or should incentives be offered to attract early participation?

DISCUSSION:

In order to manage a very large volume of work, FSIS resources would be best utilized if they could be expended in a relatively steady stream rather than all at once on a single effective date of a final regulation. If there is a reasonable and legitimate basis on which to establish differing effective dates for different processes or companies, that would assist in managing the work. Alternatively, companies might be persuaded to enter the program before the effective date, if it were in their interest to do so.

The threshold issue is to decide if phase-in is desirable. Then one can consider what would be a legitimate basis for it and finally whether it ought to be accomplished through incentives or through a series of different effective dates. This issue is equally applicable to the question of a time table for state phase in.

IV. MEASURES OF EFFECTIVENESS

BACKGROUND STATEMENT:

HACCP is a process control system which focuses on controlling hazards at critical control points. Controlling these points increases food safety and enhances public health. Agency checking of critical control points, as well as final product, is needed to determine the effectiveness of HACCP plans, and to ensure that processes remain within acceptable control levels. FSIS will have a major role in verifying that HACCP plans are effective.

ISSUE STATEMENT:

How can it be determine initially, and on a continuing basis that HACCP plans are working effectively?

QUESTIONS:

1. What types, and at what levels, of verification are necessary to verify the HACCP plan, and that the HACCP controls accurately reflect that the processes are being controlled? How might these be established? Who should do this?

2. What types of verification procedures, of critical control points, are appropriate? How should these tasks be carried out, and who will be responsible for them?

3. What types, and at what levels, of finished product testing will be necessary to support a HACCP program? How can this best be accomplished? How will this relate to finished product testing that is now required?

4. Are there certain types of data that would be useful in the development of HACCP plans. If so, which types, how should this be accomplished?

DISCUSSION:

The HACCP approach includes identifying critical control points and establishing critical limits for each critical control point. Each critical control point must have one or more measures that must be controlled to assure process control. These measures, or critical limits can be established from either chemical, physical, or microbial guidelines. These guidelines may either be currently covered by FSIS

regulation, or may be derived from other sources. Once critical control points and critical limits are established, and presumably approved by an expert approval process, then there is the issue of determining that the plan is being followed. One means of verification is a careful review of records by inspection personnel, coupled with training designed to enable those inspectors to detect evidence of false records. Another means of verification is sampling. Are there other approaches which need to be considered?

Many HACCP experts believe that the presence of an effective HACCP system makes finished product testing largely unnecessary. However, there may be a place for some such testing as a means of demonstrating the HACCP plan's effectiveness at the outset, and periodically thereafter.

V. COMPLIANCE/ENFORCEMENT

BACKGROUND STATEMENT:

FSIS must ensure that HACCP plans are being followed, and that product not meeting critical limits are properly handled. FSIS must have sufficient authority to investigate industry compliance with the HACCP requirements, and be able to take appropriate measures against those who fail to comply.

ISSUE STATEMENT:

What are the best ways to adequately enforce and ensure compliance with HACCP requirements?

QUESTIONS:

1. What types of regulatory authority are appropriate relative to a mandatory HACCP system? Are there other ways of enforcing HACCP requirements that should be considered, if so what might they be? What current enforcement/compliance activities provide models for a strategy for mandatory HACCP?

2. What types of deviations from HACCP requirements are most significant, and why? How should these deviations be handled? What is an appropriate enforcement response to repeated deviations from an approved HACCP plan which do not result in adulterated product entering commerce?

3. What should be the enforcement outcome when HACCP plans are ignored and adulterated product enters commerce?

4. Is there a need to protect plant employees from reprisals for reporting safety violations?

DISCUSSION:

Each plant is responsible for operating their HACCP system in a manner that maintains proper process control. If deviations occur, the plant, through its HACCP plan, is responsible for making adjustments to maintain process control.

If there are consistent plan deviations, and if plans are ignored, then FSIS must consider a variety of regulatory actions. These may include: increased intensity of verification; increased product testing; increased external audits; suspending a particular process; and use of either retention or recall authority. Do these existing Agency enforcement actions provide the basis for enforcement of a mandatory HACCP system.

FSIS employees are currently protected from reprisals. However, this protection does not extend to plant personnel. One question is does FSIS have the authority to extend this protection beyond its workforce. Furthermore, what are the advantages and disadvantages of protecting plant employees, assuming FSIS has the authority.

VI. RELATIONSHIP AND EFFECT OF HACCP ON CURRENT INSPECTION PROCEDURES

BACKGROUND STATEMENT:

It is expected that HACCP will create fundamental changes in the meat and poultry industry; and when such changes occurred in the past inspection also changed.

ISSUE STATEMENT:

To what extent will the possible changes in the regulated industry impact on possible changes in the current inspection system?

QUESTIONS:

1. In what ways is the industry most likely to change as a result of mandatory HACCP? In what ways will industry not be significantly affected by a mandatory HACCP requirement?

2. What might be the best way to combine HACCP and the current inspection system, and what pitfalls should be avoided? What steps can be taken to assure that the transition is orderly and effective?

3. The National Advisory Committee on Microbiological Criteria for Foods stated that agencies "could modify their inspection procedures to take advantage of the existence of HACCP plans. Thus, agency inspection for verification of HACCP plans could be in lieu of certain traditional inspection procedures rather than merely adding a new form of inspection onto existing procedures". What are the merits and shortcomings of this point of view?

4. What are the advantages and disadvantages of continuing with current regulatory programs until HACCP is fully implemented and its effectiveness is verified?

5. What relationship might exist between budgetary pressures and the implementation of HACCP? Could this impact on possible attempts to reduce regulatory in-plant presence?

DISCUSSION:

This issue involves the relationship between current levels of consumer protection during and after the move toward a mandatory HACCP regulatory environment of process control. Of necessity, this is highly speculative because HACCP is not now in place and cannot be expected for some time. However, it is useful to consider the impact on industry, and how the inspection program might respond.

To the extent that plants are operating under HACCP systems and are continuously monitoring critical control points, there should be fewer product safety problems at the end of production. If that were verified, then how should the inspection system respond. In this context should HACCP be construed as either adding to current inspection programs or replacing some aspects of existing procedures. To the extent that changes in inspection procedures may occur, should they be implemented as HACCP is developed, or should the changes be held in abeyance until full implementation of HACCP.

EXPRESS

LETTER

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